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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,579

02/10/2006

Steven Bates

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EXAMINER

GANGLE, BRIAN J

ART UNIT

PAPER NUMBER

1645

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/537,579	Applicant(s) BATES, STEVEN	
	Examiner Brian J. Gangle	Art Unit 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/24/2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-11 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) 4-7,9,10, 11, and 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's remarks and amendment to the specification, filed 5/7/2007, and amendment to the claims, filed 7/24/2007, are acknowledged. Claims 1 and 8 are amended. Claims 2-3 and 12-13 are canceled. Claims 1, 4-11, and 14-22 are pending. Claims 4-7, 9-10, and 14-22 have been withdrawn as being drawn to non-elected inventions. Claims 1 and 8 are currently under examination.

#### ***Specification***

The objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code on pages 1 and 2 is withdrawn in light of applicant's amendment thereto.

#### ***Claim Objections Withdrawn***

The objection to claim 8, because the claim is dependent on a non-elected claim, is withdrawn in light of applicant's amendment thereto.

#### ***Claim Rejections Withdrawn***

The rejection of claim 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn. The cancellation of said claim renders the rejection moot.

The rejection of claims 1 and 8 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "determining the interaction of the candidate compound with said SEC14," is withdrawn in light of applicant's amendment thereto.

The rejection of claims 1 and 8 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "method of screening or testing for candidate antifungal compounds," is withdrawn in light of applicant's amendment thereto.

The rejection of claims 1 and 8 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "providing one or more candidate compounds," is withdrawn in light of applicant's amendment thereto.

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The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase “wherein the SCE14 comprises a fragment, a function-conservative variant, an active fragment, or a fusion protein of SEC14,” is withdrawn. The cancellation of said claim renders the rejection moot.

The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Skinner *et al.* (EMBO J., 12:4775-4784, 1993), is withdrawn in light of applicant’s amendment thereto. The prior art discloses SEC14 from *Saccharomyces cerevisiae* rather than *Candida albicans*.

The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Daum *et al.* (Biochimica et Biophysica Acta, 897:240-246, 1986, IDS filed 9/1/2005), is withdrawn in light of applicant’s amendment thereto. The prior art discloses SEC14 from *Saccharomyces cerevisiae* rather than *Candida albicans*.

The rejection of claims 1-2 and 8 under 35 U.S.C. 102(b) as being anticipated by Bankaitis *et al.* (J. Cell. Biol., 108:1271-1281, 1989), is withdrawn in light of applicant’s amendment thereto. The prior art discloses SEC14 from *Saccharomyces cerevisiae* rather than *Candida albicans*.

### ***Claim Rejections Maintained***

#### ***35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1 and 8 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained essentially for the reasons set forth in the previous office action.

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The performance of the recited method steps of the claims as drawn would not lead to the stated goals of the claims.

**Applicant argues:** that the claims have been amended to focus on SEC14 derived from *Candida albicans*.

Applicant's arguments have been fully considered and deemed non-persuasive.

Applicant's arguments have not addressed the issues presented in the rejection.

Applicant's amendment is acknowledged; however, several issues with the claims are still present. These issues are restated below.

**Nature of the invention:** The instant claims are drawn to a method of screening for candidate antifungal compounds that impair SEC14 cytosolic factor enzyme (SEC14) function, comprising: a) providing *Candida albicans* SEC14; b) providing a candidate compound; c) contacting said SEC14 with said candidate compound; and d) determining the effect of the candidate compound on the activity of said SEC14 (claim 1); and to a method of screening for candidate antifungal compounds that impair *Candida albicans* SEC14 cytosolic factor enzyme (SEC14) function, comprising: a) providing *Candida albicans* SEC14 in a eukaryotic cell(s) which expresses fungal SEC14 under the control of a heterologous promoter; b) providing a candidate compound; c) contacting said eukaryotic cell(s) with said candidate compound; and d) determining the effect of the candidate compound on the *Candida albicans* SEC14 activity by assessing the effect on growth or viability of said cells (claim 8).

**Breadth of the claims:** The claims are broadly drawn in that they encompass any interaction between any compound and *Candida albicans* SEC14. The claims encompass any candidate compounds, including any compound that exists or can possibly be created.

**Guidance of the specification/The existence of working examples:** The specification provides a single working example where (presumably) full-length SEC14 from an unknown organism is produced recombinantly in *E. coli* and used in an activity assay which measures the

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transfer of phosphatidylcholine or phosphatidylinositol using liposomes. The specification does not provide a sequence or description of how to make or obtain said SEC14. The method disclosed in the specification would allow one to determine whether a candidate compound impairs or enhances SEC14 activity, but would not allow one to determine the interaction between the compound and SEC14. There is no means provided to determine if the compound is antifungal and there is no means provided that would allow one to differentiate the effect of the compound on the growth or viability of cells and the effect of the compound on SEC14..

**State of the art:** SEC14 is a well-characterized enzyme. It was originally considered essential for cell viability and Golgi secretory function, at least in *S. cerevisiae* (Lopez *et al.*, J. Cell Biol., 124:113-127, 1994, page 114, column 1, paragraph 2). However, it has since been shown that mutations in at least one of seven genes leads to SEC14-independent secretion and survival, even without SEC14 function (Rudge *et al.*, Genetics, 160:1353-1361, 2002, page 1353, column 1, paragraph 2). In addition, SEC14 is not required for viability or for secretory pathway function in the fungus *Yarrowia lipolytica* (Lopez *et al.*, abstract). While the art has SEC14 activity assays, these utilize liposomes and none determine the interaction, especially *in vivo*, of SEC14 and other compounds.

The claims, as recited, fail to provide the method steps necessary to achieve the stated goals of the claims. The goal of the method is to test antifungal compounds that impair SEC14 function. However, a compound that impairs SEC14 function will not necessarily be an antifungal compound. As shown in the art, SEC14 function is not necessary for cell viability. Some species inherently do not require SEC14, and in others, mutations can allow the use of alternate secretory pathways. Furthermore, different fungal species have different forms of SEC14. There is nothing to suggest that a compound that inhibits the activity of *Candida albicans* SEC14 would have any effect on SEC14 from another organism, let alone have an antifungal effect in all fungi.

In the method of claim 8, one is supposed to assess the viability of eukaryotic cells which are expressing *Candida albicans* SEC14, after contacting said cells with the candidate compound. First, the claims encompass all eukaryotic cells, not just fungi. One would learn nothing about the antifungal properties of a compound by contacting said compound with an insect or mammalian cell expressing *Candida albicans* SEC14. Additionally, even in cells

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which do require SEC14 for viability, if the candidate compound led to cell death, one could not determine that SEC14 was the target of the compound, only that the compound led to cell death.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use the claimed genus of proteins. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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